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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,058	06/21/2006	David Grahame Hardie	002.00270	2111
35876 7590 10/27/2009 ROGALSKY & WEYAND, LLP P.O. BOX 44 Livonia, NY 14487-0044				
EXAMINER				
SWOPE, SHERIDAN				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
10/27/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,058

Applicant(s)

HARDIE ET AL.

Examiner

SHERIDAN SWOPE

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 25 & September 23, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 16, 19-29 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 6-12, 14, 21-29 and 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 6-12, 14, 21-29 and 31-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' Request for Continuing Examination of August 25, 2009 and amendment of September 23, 2009, in response to the Final Rejection of February 25, 2009, are acknowledged. It is acknowledged that Claims 3 and 19 have been amended.

Claims 1-12, 14, 16, 19-29, 31-35 are pending.

Based on amendment of the claims and to correct prior errors in the Action of May 19, 2008, the following Restriction/Election requirement is set forth.

It is noted that the claim set of September 23, 2009 is improper because it fails to list original Claims 36-38 as cancelled.

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1 and 2, drawn to a cellular method for identifying a modulator of an AMP-activated protein kinase (AMPK) by assaying LKB1 activity.

Group II, Claims 3-5 and 16, in full, and Claims 19-20, in part, drawn to an in vitro composition comprising LKB1, STRAD, and MO25 polypeptides and a method for identifying LKB1 activity modulators using said in vitro composition.

Group III, Claims 6-12, drawn to a cell capable of expressing LKB1, STRAD, and MO25 polypeptides.

Group IV, Claim 14, drawn to a cellular method for making a composition comprising LKB1, STRAD, and MO25 polypeptides.

Group V, Claims 19-20, in part, drawn to a method for identifying LKB1 activity modulators using an intracellular composition comprising LKB1, STRAD, and MO25 polypeptides.

Group VI, Claims 21, 22, 31, and 32, drawn to a kit comprising LKB1, STRAD, and MO25 polypeptides.

Group VII, Claims 23 and 24, drawn to a method for over-expressing an LKB1.

Group VIII, Claims 25 and 26, drawn to a method for identifying a MO25 binding partner.

Group IX, Claims 27 and 28, drawn to a method for identifying a MO25 genetic defect in PJS.

Group X, Claim 29, drawn to a method for identifying a modulator of an AMPK by assaying AMPK activity.

Group XI, Claims 33 and 34, drawn to an LKB1 substrate.

Group XII, Claim 35, drawn to an antibody.

This application contains claims directed to more than one sub-invention of the generic invention. The sub-inventions are as follows.

For Group I

- Elect one specific AMPK (SEQ ID NO:) encompassed by Claims 1 and 2.
- Elect one specific LKB1 (SEQ ID NO:) encompassed by Claims 1 and 2.
- Elect one specific LKB1 substrate encompassed by Claims 1 and 2.
- Elect one of (i) without STRAD or MO25, (ii) with STRAD only, (ii) with MO25 only, (iii) with STRAD and MO25.

Based on the election of (i)-(iii), above, elect one specific STRAD (SEQ ID NO:) and one specific MO25 (SEQ ID NO:) encompassed by Claims 1 and 2.

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For Group II

- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.
- Elect one specific substrate (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.

For Group III

- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claims 6-12.

For Group IV

- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claim 14.

For Group V

- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claims 19-20.

For Group VI

- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claims 21, 22, 31, and 32.
- Elect one of (i) no AMPK polypeptide or polynucleotide, (ii) a specific AMPK polypeptide (SEQ ID NO:), or (iii) a specific AMPK polynucleotide (SEQ ID NO:) encompassed by Claims 21, 22, 31, and 32.

For Group VII

- Elect one specific LKB1 (SEQ ID NO:) encompassed by Claims 21, 22, 31, and 32.
- Elect one specific MO25 (SEQ ID NO:) encompassed by Claims 25 and 26.

For Group IX

- Elect one specific parent MO25 (SEQ ID NO:) encompassed by Claims 27 and 28.

For Group X

- Elect one specific AMPK (SEQ ID NO:) encompassed by Claim 29.
- Elect one of (i) metformin, (ii) phenformin, or (iii) AICA riboside.

For Group XI

- Elect one specific substrate (SEQ ID NO:) encompassed by Claim 29.

For Group XII

- Elect one specific antigen (SEQ ID NO:) encompassed by Claims 33 and 34.

The inventions listed as Group II relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they comprise the same or corresponding special technical feature, an in vitro composition comprising LKB1, STRAD, and MO25 polypeptides and a method for identifying LKB1 activity modulators using said in vitro composition. The products of Groups III, VI, XI, and XII are not so linked to Group II as to be encompassed by said single general inventive concept because said products do not share a common structure and function with the product of Group II. The methods of Groups IV, V, and VII-X are not linked so linked to Group II as to be encompassed by said single general inventive concept because said methods do not share the same modes of operation, functions, or effects of the methods of Group II. For each of Groups II, III, VI, XI, and XII, the sub-inventions thereof do not share a common structure and function. II. For each of Groups II, IV, V, and VII-X, the sub-inventions thereof do share the same modes of operation, functions, or effects.

Based on prior election and prosecution, Applicants have elected Group II, drawn to an in vitro composition comprising LKB1, STRAD, and MO25 polypeptides and a method for identifying LKB1 activity modulators using said in vitro composition (for example, see the Office Action of May 19, 2008, pg 7, para 4). Claims 1, 2, 6-12, 14, 21-29, 31-35 are withdrawn from further consideration as being drawn to non-elected subject matter.

In response to this communication, Applicants are required only to elect:

For Group II

- Elect one specific LKB1 (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.
- Elect one specific STRAD (SEQ ID NO:), or one specific cell from which one specific endogenous STRAD can be isolated, encompassed by Claims 3-5, 16, and 19-20.
- Elect one specific MO25 (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.
- Elect one specific substrate (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.

If Applicants have any questions about this election requirement, they are welcome to contact the Examiner.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should Applicants traverse on the ground that the inventions are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is requested that Applicants cite the serial number of the Application on every page of filed documents.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652